

Message Text

UNCLASSIFIED

PAGE 01 STATE 298846

21

ORIGIN HEW-06

INFO OCT-01 AF-06 ARA-10 EUR-12 ISO-00 OES-05 MED-03 /043 R

DRAFTED BY: DHEW/FDA:JRWEINROTH, MD.:AMS

APPROVED BY: OES/APT/BMP:MBEAUBIEN

DHEW/OIH:MACODDING

AF/S:FBCRUMP (INFO)

EUR/CE:BAFLATIN (INFO)

ARA/NSC-IG:RJBLOOMFIELD (INFO)

EUR/NE:KHSHIRLEY (INFO)

----- 093507

R 190127Z DEC 75

FM SECSTATE WASHDC

TO AMEMBASSY BUENOS AIRES

AMEMBASSY SANTIAGO

AMEMBASSY BOGOTA

AMEMBASSY SAN JOSE

AMEMBASSY SANTO DOMINGO

AMEMBASSY QUITO

AMEMBASSY SAN SALVADOR

AMEMBASSY KINGSTON

AMEMBASSY MEXICO

AMEMBASSY THE HAGUE

AMEMBASSY PANAMA

AMEMBASSY LIMA

AMEMBASSY PRETORIA

AMEMBASSY BERN

AMEMBASSY CARACAS

AMCONSUL RIO DE JANEIRO

INFO AMEMBASSY BRASILIA

UNCLAS STATE 298846

E.O. 11652: N/A

TAGS: OGEN, ETRD, TBIO, AR, BR, CI, CO, CS, DR, EC, ES, JM,

MX, NL, PN, PE, SF, SZ, VE

SUBJ: FDA ADVISORY - DEFECTIVE PACKAGING, LOSS OF STERILITY

REF: STATE 208404, 22477

UNCLASSIFIED

UNCLASSIFIED

PAGE 02 STATE 298846

1. FDA ADVISES THAT:

PRODUCT: CORDIS DUCOR BRAND ANGIOGRAPHIC CATHETERS: FEMORAL - LEFT CORONARY B, OPEN END, NO SIDE HOLES. EACH CATHETER IS PACKAGED IN AN ENVELOPE WHICH IS MYLAR ON ONE SIDE AND SURGICAL PAPER ON THE OTHER SIDE. THE ENVELOPE IS LABELED IN PART: "DUCOR ANGIOGRAPHIC CATHETERS STERILE. NON PYROGENIC. XXX OPEN END. NO SIDE HOLE. XXX GUIDE WIRE DIAMETER .038 IN. XXX FOR ONE USE ONLY XXX CONTENTS OF UNOPENED AND UN-DAMAGED PACKAGE ARE STERILE AND NONPYROGENIC XXX CORDIS CORPORATION, MIAMI, FLORIDA XXX". THE PACKAGES ARE FURTHER LABELED AS FOLLOWS:

- A. CATALOG NO. 524-740: "FEMORAL - LEFT CORONARY B, 1 FRENCH 7. 100 CM. XXX
- B. CATALOG NO. 524-742: "FEMORAL - LEFT CORONARY B, 11 FRENCH 100 CM. XXX
- C. CATALOG NO. 524-842: "FEMORAL - LEFT CORONARY 2 FRENCH 8, 100 CM. XXX
- D. CATALOG NO. 524-844: "FEMORAL - LEFT CORONARY 3 FRENCH 8. 100 CM. XXX

THE CATHETERS ARE PACKAGED FIVE PER BOX WHICH IS SIMILARLY LABELED. THE BOX IS ADDITIONALLY LABELED IN PART "XXX FIVE STERILE, NON-PYROGENIC DISPOSABLE UNITSXXX". THE INITIAL RECALL INVOLVED CATALOG NO. 524-842, LOT NUMBERS 114000, 3045095, AND 3045144. THE RECALL HAS NOW BEEN EXTENDED TO INCLUDE THE FOLLOWING CATALOG NUMBERS AND LOTS:

CATALOG NO. 524-740, LOT NO. 3075187; CATALOG NO. 524-742, LOT NUMBERS 3065202 AND 3065204; CATALOG NO. 524-842, LOT NUMBERS 114000, 3045095, 3045144, 3065182, 3075024; CATALOG NO. 524-844, LOT NUMBERS 3075018 AND 3075083.

MANUFACTURER:

THE CORDIS CORP.
3915 BISCAYNE BLVD.
MIAMI, FLORIDA 33137

UNCLASSIFIED

UNCLASSIFIED

PAGE 03 STATE 298846

REASON FOR ADVISORY EXTENSION: EXAMINATION OF SUBSAMPLES OF ABOVE MENTIONED CATALOG NUMBERS AND LOTS REVEALED DEFECTIVE SEALS ON DISTAL END OF ENVELOPES WHICH PROVIDES AN ENTRY-WAY INTO ENVELOPE ITSELF. IT IS THIS ENVELOPE WHICH PROVIDES A STERILITY BARRIER.

2. FOREIGN CONSIGNEES AS FOLLOWS:

VIGLIREAD S.A.C.I.F.I.A.
AV. ENTRE RIOS 166-4B
BUENOS AIRES
ARGENTINA, S.A.

SR. E.N, AVEGLIANO
DEARMEDELEC S.A.I.C.
AV. JURAMENTO 4182/86
BUENOS AIRES, ARGENTINA

COSIMEX COMERCIO IMPORTACAO
EXPORTACAO S.A.
AV. IPIRANGA 1097
SAO PAULO, BRAZIL S.A.

DIANA ELECTROMEDICINA
RUA DIO BRANCO 133
RIO DE JANEIRO, BRAZIL

SANTIAGO FERNANDO
JOAO - JULLAN 296, APT. 22
SAO PAULO, BRAZIL, S.A.

SOCIEDAD IMPORTADORA GRASSI LTDA
R. SENADOR DANTAS, 76 - SOBRELOJA
S/LOJA 7C-06
RIO DE JANEIRO, BRAZIL

SR. GERMAN B. VERDUGO
DICOR LTDA.
HUERIANOS 1160 OF 704
SANTIAGO, CHILE

UNCLASSIFIED

UNCLASSIFIED

PAGE 04 STATE 298846

GERENTE GENERAL PROMEX, S.A.
CASILLA 9088
SANTIAGO, CHILE

MAX MEYER
APARTADO AEREO 12220
BOGOTA, COLOMBIA

COSTA RICA DENTAL AND MEDICAL SUPPLY CO.,
APARTADO 434 Y 10174
SAN JOSE, COSTA RICA

CHAN DR. ANGEL
INSTITUTO DEL CORAZON
AV. TTE. GARCIA GUERRERO

NO. 265
SANTO DOMINGO, R.D.

GAMMA INDUSTRIAS Y COMERCIO
CASTILLA 1132 QUITO, ECUADOR S.A.

ORTO MEDIC
IMBABURA 979 Y BOLIVAR
P.O. BOX 1230
QUITO, ECUADOR, S.A.

DR. EFRAIN PAREDas C.
ORTOMEDIC
LA HABANA 811, Y FCO. SEGURA
GUAYAQUIL, ECUADOR

WOLFF, MARCEL J.
CALLE ARCE NO. 1219
SAN SALVADOR, EL SALVADOR

ATCO LIMITED
1 DUMFRIES ROAD
KINGSTON 10, JAMAICA

MEDICINA TECNICA S.A.
ATT. DR. COSIO PASCAL
UNCLASSIFIED

UNCLASSIFIED

PAGE 05 STATE 298846

ALVARO OBREGON 242-4 PISO
MEXICO CITY, D.F., MEXICO

EQUIPO PARA HOSPITALIS S.A.
TONALA 161
MEXICO 7 D.F., MEXICO

CORDIS EUROPA N.V.
BONDED WAREHOUSE
SCHIPHOL AIRPORT
AMSTERDAM, THE NETHERLANDS

CORDIS EUROPA N.V.
P.O. BOX 38
RODEN, NETHERLANDS

NELSON GOMEZ
HOSPITAL SEGURO SOCIAL
APARTADO 10198
REPUBLIC OF PANAMA

GERENTE GENERAL

PROMED S.A.
P.O. BOX 6281
PANAMA 5, PANAMA

SR. ROLAND DEFAGO
SERVICIO Y MANTENIMIENTO
CASTILLA 4847
LIMA 100, PERU

MESSRS. FREDERICK C. MARCUS AND CO.,
P.O. BOX 3039
CAPE TOWN, SOUTH AFRICA

PROVEX S.A. SR. ERNESTO REIMANN
C/O CASA PETRI VIA LIDO 8
CH 6612 ASCONA, SWITZERLAND

SR. JOHN G. GUGIG
EQUILAB C.A.
UNCLASSIFIED

UNCLASSIFIED

PAGE 06 STATE 298846

APARTADO 60.497
CARACAS 106, VENEZUELA

3. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO
DETERMINE IF THEY ARE AWARE OF PROBLEMS OF DEFECTIVE PACKAGING.
ANY INCOMPLETELY SEALED UNITS IN ORIGINAL PACKAGES ARE TO
BE RETURNED TO THE CORDIS CORPORATION MIAMI, FLORIDA DIRECTLY.
ANY QUESTIONS CONSIGNEES MAY HAVE REGARDING THIS ADVISORY
SHOULD BE DIRECTED TO THE MANUFACTURER. KISSINGER

UNCLASSIFIED

NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, DATA, RECALLS
Control Number: n/a
Copy: SINGLE
Draft Date: 19 DEC 1975
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1975STATE298846
Document Source: CORE
Document Unique ID: 00
Drafter: DHEW/FDA:JRWEINROTH, MD.:AMS
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: D750441-0429
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1975/newtext/t19751227/aaaaaxkj.tel
Line Count: 257
Locator: TEXT ON-LINE, ON MICROFILM
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 5
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: 75 STATE 208404
Review Action: RELEASED, APPROVED
Review Authority: KelleyW0
Review Comment: n/a
Review Content Flags:
Review Date: 18 JUN 2003
Review Event:
Review Exemptions: n/a
Review History: RELEASED <18 JUN 2003 by ReddocGW>; APPROVED <09 FEB 2004 by KelleyW0>
Review Markings:

Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
06 JUL 2006

Review Media Identifier:
Review Referrals: n/a
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY - DEFECTIVE PACKAGING, LOSS OF STERILITY
TAGS: OGEN, ETRD, TBIO, AR, BR, CI, CO, CS, DR, EC, ES, JM
To: BUENOS AIRES MULTIPLE
Type: TE
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 06 JUL 2006